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EXAMINER	
HARTLEY, M	
ART UNIT	**PAPER NUMBER**
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DATE MAILED: 12/05/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☑ This application has been examined for restriction purposes only. ☑ Responsive to communication filed on 8.12.94 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire — month(s), 30 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☑ Claims 1-36 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☐ Claims _____ are rejected.
5. ☐ Claims _____ are objected to.
6. ☑ Claims 1-36 are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a) (2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825.

APPLICANT IS GIVEN ONE MONTH FROM THE DATE OF THIS LETTER WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 CFR 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Direct the response to the undersigned.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-3, 5, 6, 26 and 31, drawn to a reagent for preparing a chelating compound, and the composition of a chelating agent, which is a monoamine, diamine, thiol containing chelator, classified in Class 558, subclass 254;

Group II. Claims 7-10, drawn to metal chelating compounds comprising of peptides with specific amino acid sequences bound to a chelating group, classified in Class 424, subclass 1.69;

Group III. Claims 11, 12 and 15-17, drawn to peptides with defined amino acid, classified in Class 530, subclass 300+;

Group IV. Claims 18-21, 24, 28, 30, 34 and 36 drawn to a scintigraphic imaging agent and methods of preparing the scintigraphic imaging agent, classified in Class 424, subclass 9.34;

Group V. Claim 22, drawn to a method of peptide synthesis, classified in Class 530, subclass 334;

Group VI. Claims 13, 14, drawn to a peptide with specific binding to receptor molecules, classified in Class 530, subclass 388.

Group VII. Claims 25, 27, 29, 32, 33, drawn to a radiotherapeutic agent, classified in Class 424, subclass 1.11;

3. The inventions are distinct, each from the other because of the following reasons:

Inventions IV and V are distinct from each other because of the different materials, steps, and conditions necessary to perform each method. For example, Group IV requires reacting a chelating agent with a radionuclide in the presence of a reducing agent while Group V requires a specific method of peptide synthesis. The different steps of each method are evident from the individual claims.

Inventions I and II, as well as III and VI, and VII, are related as mutually exclusive species in intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (M.P.E.P. § 806.04(b), 3rd paragraph), and the species are patentably distinct (M.P.E.P. § 806.04(h)).

In the instant case, the intermediate product is deemed to be useful in anyone of the final products, i.e., a labeled agent, an scintigraphic imaging agent, a therapeutic agent, a specific binding moiety, a composition of matter comprising amino acid

sequences, etc., and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

Inventions IV-V and II-IV, as well as VI and VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case a scintigraphic imaging agent can be prepared using other reducing agents and this method can be used to prepare a variety of different compositions and the method of solid phase peptide synthesis can be used to prepare materially different compositions of matter.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Upon election of any of the previously mentioned groups, applicant is further required to make an election of species with regard to the compound or composition to be examined. The claims of the present application contain a multitude of species. An election of species will require the applicant to elect a specific compound by specifing the various substituents placed on the elected ligand, or elect a specific composition in reference to the "Markush" group of amino acid sequence structures listed in the applicatable claims. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

The claims as presented contain such a vast multitude of "possibilities and permutations" that it is not possible to identify each and every species encompassed in the claims. Accordingly, to facilitate election, applicant is required to elect a single specific compound including the structure and upon such election the Examiner will review the claims and indicate (a) which compounds are so similar thereto as to be a part of the elected matter and, (b), by such indication (i.e. by exclusion) which compounds are drawn to non-elected matter.

It is considered that the "Markush" type claims encompassing such species are directed to multiple "independent and distinct inventions" since the species encompass compounds that are so unrelated and diverse that a prior art reference anticipating the claims with respect to one of the species will not render the claims obvious under 35 U.S.C. 103 with respect to any of the other species. Further, these claims encompass species that are considered to be independent since they are unconnected in operation; one does not require the others for ultimate use and the specification does not disclose a dependent relationship between them. Moreover, there are encompassed species that are considered to be distinct from the others on the basis of their properties. Also, it is an undue burden on the PTO to act on more than one invention in one case. Thus, this application contains species that are capable of supporting separate patents under 35 U.S.C. 121.

Accordingly, applicant is required to make a provisional election of a single independent and distinct specie as noted

supra, prior to the examinations of said claims on the merits. This election will be given effect in the event that the "Markush" type claim(s) is (are) not found allowable, at which time the "Markush" type claim(s) directed solely to the elected species, with claims directed solely to the nonelected species being held withdrawn from further consideration. It should be noted that an election of species has been held to be tantamount to a requirement for restriction (In re Herrick, 1958 C.D. 1 and In re Joyce, 1958 C.D. 2) and enjoys the benefit of 35 U.S.C. 121.

6. Applicant's response must include a provisional election as noted supra, even though the requirement be traversed (37 CFR 1.143). Applicant is also advised that any traversal must be supported by specific argument(s) in order to perfect the right to petition in the event that the provisional requirement is given effect in the event noted supra. Applicant is also advised that arguments adequate to cause withdrawal of this requirement would warrant the ultimate conclusion that all species are patentably indistinct and a reference for one species would be considered a reference as to all species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

7. A telephone call was made to Kevin E. Noonan on 11-29-95 to request an oral election to the above restriction requirement, but did not result in an election being made.

The Attorney requested a written restriction requirement.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Michael Hartley whose telephone number is (703) 308-4411. The

examiner can usually be reached on Monday through Friday from 7:30 am to 4:00 pm in the eastern time zone. The facsimile numbers for group 1200 are (703) 308-4556 or (703) 305-3592.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist, can be reached on (703) 308-1701.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Date: 11·30·95

Hartley/mbb

GARY E. HOLLINDEN, PH.D.
PRIMARY EXAMINER
GROUP 1200